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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/687,281 10/13/00 KIM

H. GI 5387

EXAMINER

HM12/0517

AMERICAN HOME PRODUCTS CORPORATION
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PATENT & TRADEMARK OFFICE 2B
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GLITTMAN, H	
ART UNIT	PAPER NUMBER

1651

DATE MAILED:

05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/687,281

Applicant(s)

KIM ET AL.

Examiner

Harry J Guttman

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 1-10 are pending.

Claims 1-7 are examined on their merits insofar as they read on the elected invention.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a mixture including an osteogenic protein and hyaluronic acid derivative, classified in class 514, subclass 21, for example.
- II. Claim 8, drawn to a mixture comprising a hyaluronic acid derivative, classified in class 514, subclass 23, for example.
- III. Claims 9 and 10, drawn to a method of making injectable hyaluronic acid derivative, classified in class 424, subclass 423, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition may include ingredients not included in the process of making.

Inventions I with III, and I with II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have functions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Barbara Gyure on May 14, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the term "pore formers". This term is ambiguous and requires clarification in the claim language. For purposes of examination, pore formers will include PEG, sodium bicarbonate, sucrose, NaCl and citric acid (see specification page 4).

Claims 1 (and its dependents) and 7 recite the term "derivatives". This term is ambiguous and requires clarification in the claim language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubler et al. (1990). Kubler et al. (1990) disclose an injectable mixture of BMP and hyaluronic acid (Table 7).

Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanis et al. (CZ 283073). Vanis et al. (CZ 283073) disclose a liquid mixture comprising calcium phosphate, hyaluronic acid and BMP (abstract).

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wozney et al.(US 6187742). Wozney et al.(US 6187742) teach the combination of osteogenic proteins (including BMP-7, which is OP-1, and preferably BMP-2; column 3 lines 26-50)) with a number of carriers including porous particulate polymers (including PEG; column 4 line 59- column 5 line 5), sucrose (column 5 lines 40-42), hyaluronic acid and tricalcium phosphate (column 5 lines 50-56). Wozney et al. discuss the use of the preparation by injection through a syringe (column 5 line 63).

Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Johansson (US 5464440). Johansson (US 5464440) disclose the use of BMP with hyaluronic acid and tricalcium phosphate in a polymer type carrier (column 2 lines 25-35).

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al. (US 5752974). Rhee et al. (US 5752974) disclose the combination of BMP-2 or BMP-7 (column 7 lines 15-19), PEG (column 5 line 5-8), a crosslinked hyaluronic acid (column 5 lines 51-55) or hyaluronic acid (column 6 lines 31-34), and tricalcium phosphate (column 6 lines 50-57). This combination is designed for injection (column 8 lines 56-64, and column 9 lines 50-53).

Art Unit: 1651

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et al. (US 5939323). Valentini et al. (US 5939323) disclose the combination of esterified hyaluronic acid (column 5 lines 32-48), NaCl (column 6 lines 4-19), and BMP (including BMP-2; column 6 line 34-38, and example 6). These can be injectable pastes (e.g., see example 1).

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Schug et al. (WO 9722308) and under 35 U.S.C. 102(e) as being anticipated by Suhonen et al (US 6132214). The US equivalent will be referenced for convenience. Suhonen et al (US 6132214) disclose the combination of esterified hyaluronic acid (column 5 lines 57-59), tricalcium phosphate (column 5 lines 1-5), PEG (column 5 lines 50-52), and BMP (including BMP-2 and OP-1/BMP-7; column 6 lines 24-28). The composition is designed for use in an injection instrument (column 5 lines 63-66).

Additional references not cited in this action have been listed in PTO-892 to establish the state of the art.

Any inquiry concerning this communication should be directed to Harry J. Guttman, Ph.D. at telephone number (703) 305-0159. The examiner can normally be reached during the hours of 07:30 to 16:00 Eastern Time, Mon.-Thurs. If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number for Art Unit 1651 is (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

All internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be

Art Unit: 1651

identified or exchanged unless there is of record an express waiver of the confidentiality requirements of 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published in the Patent and Trademark Office Official Gazette on 25 February 1997 at 1195 OG 89.

H.J.G. 16 May 2001

A handwritten signature in black ink, appearing to read "Harry J. Guttman", with a stylized, flowing script.

Harry J. Guttman, Ph.D.
Examiner, 1651
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A handwritten signature in black ink, appearing to read "Jon P. Weber", with a stylized, flowing script.

Jon P. Weber, Ph.D.
Primary Examiner